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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Prince et al. Attorney Docket No.: 1324.030A
Serial No.: 10/635,725 Group Art Unit: 1645
Filed: August 6, 2003 Examiner: Ford, Vanessa
Title: FOULBROOD TREATMENTS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner For Patents, Board of Patent Appeals and Interferences, P.O. Box 1450, Alexandria, VA 22313-1450 on October 26, 2006.

Kathy Smith Dias

Kathy Smith Dias
Attorney for Appellants
Registration No. 41,707

Date of Signature: October 26, 2006

To: Mail Stop Appeal Brief-Patents
Commissioner for Patents
Board of Patent Appeals and Interferences
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Dear Sir:

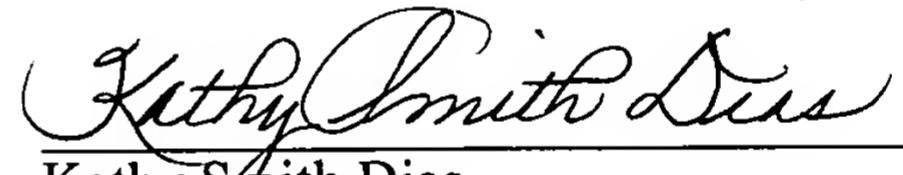
This paper is filed in response to the Notice mailed September 26, 2006 for the above-referenced patent application. A response to the Notice is due on or before October 26, 2006, and therefore, this response is timely filed.

REMARKS

The Notification of Non-Compliant Appeal Brief states that Appellants' Brief allegedly does not contain a concise explanation of the subject matter defined in each of the independent claims, referring to the specification by page and line number. Additionally, according to the Notification, Appellants' statement of rejection on page 5 of the Appeal Brief is incorrect.

In response to the Notification, enclosed herewith is an amended Appellants' Brief which is substantively identical to the Brief originally filed on October 20, 2004 but which now contains an expanded Summary of Claimed Subject Matter section and includes the requisite references to the specification. Also, the Status of Claims section is revised to reflect the rejection as enunciated by the Advisory Action dated April 11, 2006.

The Brief filed herewith is, therefore, complete and prompt consideration of the appeal is respectfully requested.



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Dated: October 26, 2006

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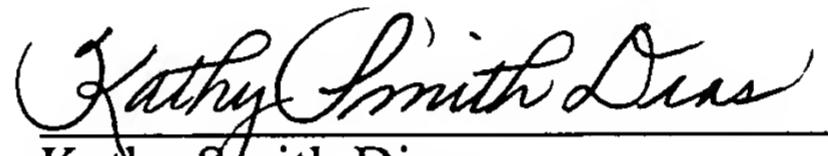


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Attorney for Appellants
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Date of Signature: October 26, 2006

To: Mail Stop Appeal Brief-Patents
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Dear Sir:

**APPELLANTS' APPEAL BRIEF TO THE BOARD OF
PATENT APPEALS AND INTERFERENCES**

This is an appeal from a Final Rejection, mailed October 19, 2005, rejecting claims 1-16, that is, all the claims under consideration in the above-identified application. A Notice of Appeal with a Request for a Three-Month Extension of Time was timely filed on April 19, 2006 and received by the United States Patent and Trademark Office on April 24, 2006. This Appeal Brief

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is therefore due on June 24, 2006, and is timely filed. This Brief is accompanied by a check in the amount of \$500.00 for payment of the requisite fee set forth in 37 C.F.R. §1.17(c).

The format and content of Appellants' brief is believed to be in compliance with the requirements set forth in 37 C.F.R. §41.37(c). However, if Appellants' brief does not comply with the requirements set forth in 37 C.F.R. §41.37(c), Appellants' request notification of the reasons for noncompliance and the opportunity to file an amended brief pursuant to 37 C.F.R. §41.37(d).

(i) Real Party in Interest

This patent application is assigned to University College Cardiff Consultants Ltd., a company existing under the laws of Great Britain, having offices at 56 Park Place, Cardiff CR1 3XR United Kingdom, by virtue of an Assignment executed on June 14, 2006 and June 15, 2006 and recorded with the United States Patent and Trademark Office at Reel 017827/Frame 0596 on June 22, 2006. Therefore, the real party in interest is University College Cardiff Consultants Ltd.

(ii) Related Appeals and Interferences

To the knowledge of Appellants and Appellants' undersigned legal representative, there are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

(iii) Status of Claims

This patent application was filed as a continuation of a continuation of a PCT International application on August 6, 2003. As filed, the application contained claims 1-16 of which one (1) claim was an independent claim (claim 1).

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In an initial Office Action dated April 25, 2005, claims 1-16 were rejected under 35 U.S.C. § 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention. Claims 1 and 7-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Oldroyd et al. (Aust. J. Agric. Res., 1989, 40(3), p. 691-698), Hansen et al. (Tidsskrift for Planteavl, 1988, Vol. 92, No. 1, p. 11-15) and Wilson et al. (Can. J. Microbiol., June 1970, 16(6) 521-526). Claims 1-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Hoopingarner et al. (American Bee Journal, 1988, Vol. 128, No. 2, p. 120-121). In Appellants' response dated July 25, 2005, claim 1 was amended.

In a second and final Office Action dated October 19, 2005, rejections under 35 U.S.C. 112, second paragraph, 102 (b) and 102/103 from the previous Office Action were withdrawn. Only the rejection of claims 1 and 7-16 under 35 U.S.C. § 102(b) in light of Oldroyd was maintained. In Appellants' Response of January 19, 2006, Appellants' requested withdrawal of the rejection under 35 U.S.C. § 102(b) for the reasons set forth in the response without further amendment.

Appellants received an Advisory Action dated April 11, 2006, which indicated that the rejection of claims 1 and 7-16 under 35 U.S.C. 102(b) was maintained. The Advisory Action also indicated that the rejection of claims 1-16 under 35 U.S.C. §§ 102/103 was withdrawn. However, this rejection was withdrawn previously in response to the initial Office Action.

A Notice of Appeal to the Board of Patent Appeals and Interferences was mailed on April 19, 2006 with a request for a three-month extension of time and fee therefor. The Notice of Appeal was received at the United States Patent and Trademark Office on April 24, 2006.

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Although the advisory action of April 11, 2006 indicates for the first time that claims 2-6 are objected to as being dependent on a rejected base claim, there is no suggestion that claims 2-6 would be allowable if rewritten in independent form to include all the limitations of the rejected base claim. It is unclear, therefore, whether claims 2-6 would be allowable if rewritten.

The status of the claims, according to the Advisory Action, appears to be as follows:

Allowed Claims	-	None
Claims Objected to	-	2-6
Claims Rejected	-	1 and 7-16
ClaimsAppealed	-	1 and 7-16.

Appellants are appealing the rejection of claims 1 and 7-16, based on the assumption that the characterization of claims 2-6 as objected to as enunciated in the Advisory Action is correct.

(iv) Status of Amendments

The claims currently under appeal were presented in an amendment included in Appellants' Response to the initial Office Action dated April 25, 2005 and entered by the Examiner. No amendments have been presented subsequent to this initial amendment. The claims as set out in the Claims Appendix are the claims as amended in response to the initial Office Action.

(v) Summary of Claimed Subject Matter

The invention relates to a method of treating foulbrood disease in bees using non-pathogenic microorganisms. Introduction into the hive of non-pathogenic microorganisms that either a) produce an antibiotic or b) compete with bee pathogens provides a safe and efficient, biologically controlled system for eradicating or preventing disease caused by pathogenic microorganisms (page 4 paragraph [0014] and [0017]). The claimed subject matter, as recited in independent claim 1, therefore, is a composition for treating foulbrood, the composition comprising 1) an inoculum containing one or more microorganisms that are non-pathogenic to bees for producing a microflora having therapeutic or prophylactic efficacy against the bee disease and 2) an apicultural delivery vehicle for delivering the inoculum. The apicultural delivery vehicle for delivering the inoculum, as recited in dependent claims 2-6 is selected from traditional apicultural delivery vehicles: a patty, a syrup, a drench, a dusting and a paste (page 5, paragraph [0022] and paragraphs [0025] to [0030].)

(vi) Grounds of Rejection To Be Reviewed On Appeal

1. Claims 1 and 7-16 are rejected under 35 U.S.C. §102(b) as being anticipated by Oldroyd et al. (*Aust. J. Agric. Res.*, 1989, 40(3), p. 691-698.)

(vii) Arguments

I. *Rejection of Claims 1-16 under 35 U.S.C. 102(b)*

A. APPELLANT'S POSITION

Claims 1 and 7-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Oldroyd et al. (*Aust. J. Agric. Res.*, 1989, 40(3), p. 691-698.) Appellants respectfully submit that this rejection is improper, since one or more of Appellants' claimed elements is not disclosed in the cited reference.

B. SUPPORT FOR APPELLANTS' POSITION

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co. of California, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Anticipation under 35 U.S.C. §102, therefore, requires the presence in a single prior art disclosure of each and every element of a claimed invention.

Appellants' claimed invention, as recited in independent claim 1 of the instant application, recites a composition for the treatment or prophylaxis of a bee disease, the composition comprising: a) an inoculum containing one or more microorganisms that are non-pathogenic to bees for producing a microflora having therapeutic or prophylactic efficacy against the bee disease; and b) an apicultural delivery vehicle for delivering the inoculum to a component of a bee hive or to a bee colony that is susceptible to or infected with the bee disease, whereby a remedial and/or protective microflora is established within the hive or the bee colony. Thus, a primary feature of the claimed composition is an inoculum of one or more microorganisms that are *non-pathogenic* to bees.

In order for Oldroyd to anticipate Appellants' claims, therefore, Oldroyd must teach an inoculum containing one or more microorganisms that are non-pathogenic to bees. It does not. The propriety of the rejection of the present claims rests on whether one of skill in the art would, based on the teachings of the Oldroyd reference, in particular, and the literature as a whole, would conclude that *Paenibacillus larvae* subsp. *larvae* subsp. *larvae* (formerly *B. larvae*) is a non-pathogenic microorganism. Appellants' position is that they would not.

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It should be noted that, as evidenced by Heyndrickx et al. (p.990), there have been changes in nomenclature with respect to *Bacillus* taxonomy since the present application was filed. The organism referred to in Oldroyd as *Bacillus larvae* is now known as *Paenibacillus larvae* subsp. *larvae*. Accordingly, the two terms are used herein to refer to the same organism, i.e., the causative agent for American foulbrood.

As a preliminary matter, contrary to the statement on page 3 of the Advisory Action that Appellants do not agree with the definition of non-pathogenic as proposed by the examiner, the definition of the term “non-pathogenic” as used in independent claim 1 is not in dispute. A **non-pathogen** is a microorganism that is not able to cause disease in a plant, animal or insect. Conversely, a **pathogen** is a microorganism that is able to cause disease.

Relying on the transitional or open claim language “comprising” in independent claim 1, the examiner urges that other components may be present in Appellants’ claimed composition. According to the Advisory Action, therefore, the rejection was on the grounds that Oldroyd et al. teach that honeybee colonies were treated with various preparations of oxytetracycline hydrochloride (OTC), an antibiotic to which *B. larvae* is sensitive, at the time of inoculation with *Bacillus larvae* spores. Furthermore, the examiner relies on the statement in Oldroyd et al. that “*B. larvae* was cultured from adult bee samples from colonies...that were American Foulbrood (AFB) disease-free at the time of sampling and did not subsequently develop disease signs.” From this, the examiner concludes that Oldroyd teaches a composition containing a microorganism that is non-pathogenic to bees, thereby anticipating the composition as claimed by Appellants. There is, however, no evidence in the literature, not even in Oldroyd, to support this conclusion.

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Applicants respectfully submit that a proper reading of Oldroyd makes it clear that *B. larvae* is *not*, as the Action maintains, non-pathogenic to bees. Oldroyd, therefore, cannot anticipate the present invention.

It is quite clear from a survey of the literature, including Oldroyd et al., that *Paenibacillus larvae* subsp. *larvae* is the primary larval pathogen of honey bees (see Evidence appendix.) Oldroyd clearly teaches that which is well known in the art, that is, that American foulbrood (AFB) is caused by the bacterium *Bacillus larvae*.

The literature, including Oldroyd, further teaches that oxytetracycline hydrochloride (OTC) therapy is commonly used to control European foulbrood (EFB) and is used to control AFB in Tasmania and some areas of the United States. One study demonstrated that *Paenibacillus larvae* subsp. *larvae* isolated from Australian sources continue to be very sensitive to OTC and that no resistance to OTC appears to have developed over the past fifteen or sixteen years.

However, a proper reading of Oldroyd would not lead one of skill in the art to conclude that *B. larvae*, even in the presence of OTC, is a non-pathogenic organism useful for the treatment or prophylaxis of a bee disease. Rather, Oldroyd teaches that *Bacillus larvae* is a highly pathogenic organism, even in the presence of OTC, and that frequently treatment with OTC suppresses disease signs.

Oldroyd presents the results of a study of the effect of OTC treatment on American foulbrood. In these studies, honeybee colonies were inoculated with *Bacillus larvae* spores to induce the disease. Additionally, some of the colonies were treated with OTC preparations at two different times: 1) at the same time that the colony was inoculated with the *B. larvae* spores

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or 2) after American foulbrood disease signs had developed in the colony. Control colonies were inoculated with *B. larvae* to initiate infection, but no OTC was given.

The relevant portions of Oldroyd appear on pages 692 and 693 and reads as follows:

"Treatment of Colonies with Oxytetracycline Hydrochloride

Experiment 1: Effect of OTC as a preventative of AFB disease

On 21 November 1986, 10 colonies were inoculated with *B. larvae* spores. Five of these colonies were treated with 1 g of OTC (Terramycin 50R Pfizer) dissolved in 500 ml of 50% v/v sucrose syrup (S:S) at the time of inoculation. The other five colonies were treated with 500 ml S:S only."

"Results

Experiment 1: Effects of OTC as a Preventative of AFB Disease

All control colonies [emphasis added] inoculated with *B. larvae* spores developed disease signs within 40 days (Fig.1). OTC treatment at the time of inoculation prevented the development of disease signs for 58 days in one hive, 291 days in another hive and two other colonies became diseased in mid-summer, more than 1 year after their inoculation with *B. larvae* spores. *AFB disease was prevented by OTC treatment at the time of inoculation in 1 colony only* (Fig.1)."

The results show that all of the colonies that were inoculated with *B. larvae* in the absence of OTC became diseased. Additionally, four colonies of five (i.e. 80%) inoculated simultaneously with *B. larvae* and OTC developed foulbrood disease. Therefore, even in the presence of an antibiotic to which it is sensitive, *B. larvae* are able to cause disease. Not surprisingly, Oldroyd (abstract) states that *B. larvae* was subsequently cultured from adult bee

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samples from colonies that did not develop disease signs. These colonies, however, were treated with OTC. Oldroyd does not suggest that these colonies are disease free subsequent to inoculation with *B. larvae* because *B. larvae* is not a pathogen; rather, Oldroyd concludes that these results show that recommended treatments for European foulbrood (EFB), i.e., treatment with OTC, essentially suppress signs of AFB disease.

It is therefore, inconceivable that a person of skill in the art would conclude, based on all the evidence including the teachings of Oldroyd, that *Paenibacillus larvae* subsp. *larvae* (formerly known as *B. larvae*) is non-pathogenic to bees.

C. CONCLUSION

Appellants respectfully request reversal of the 35 U.S.C. §102(b) rejections of claims 1 and 7-16 set forth in the Final Office Action. For the reasons discussed herein, Appellants respectfully submit that the §102(b) rejection based on Oldroyd is clearly erroneous since the cited reference does not teach an inoculum containing one or more microorganisms that are non-pathogenic to bees. Accordingly, reversal of all rejections is respectfully requested.



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(viii) CLAIMS APPENDIX

1. A composition for the treatment or prophylaxis of a bee disease, the composition comprising:
 - (a) an inoculum containing one or more microorganisms that are non-pathogenic to bees for producing a microflora having therapeutic or prophylactic efficacy against the bee disease; and
 - (b) an apicultural delivery vehicle for delivering the inoculum to a component of a bee hive, or to a bee colony that is susceptible to or infected with the bee disease, whereby a remedial and/or protective microflora is established within the hive or the bee colony.
2. The composition of claim 1, wherein the apicultural delivery vehicle is selected from:
 - (a) a patty;
 - (b) a syrup;
 - (c) a drench;
 - (d) a dusting; and
 - (e) a paste.
3. The composition of claim 2, wherein the apicultural delivery vehicle is a patty selected from:
 - (a) a sugar patty; and
 - (b) a sugar and fat extender patty.
4. The composition of claim 2, wherein the apicultural delivery vehicle is a syrup comprising sugar and water.
5. The composition of claim 2, wherein the apicultural delivery vehicle is a dusting comprising sugar.

6. The composition of claim 2, wherein the apicultural delivery vehicle is a paste comprising a pollen substitute.
7. The composition of claim 1, wherein the inoculum comprises one or more microorganism(s) that produce one or more antibiotic(s) active against one or more bee pathogen(s).
8. The composition of claim 7, wherein the antibiotic(s) are active against at least one of *Melissococcus pluton* and *Paenibacillus larvae* subsp. *larvae* subsp. *larvae*.
9. The composition of claim 7, wherein the antibiotic(s) are bacteriolytic.
10. The composition of claim 7, wherein the antibiotic(s) are the anti-*Melissococcus pluton* and/or the anti-*Paenibacillus larvae* subsp. *larvae* subsp. *larvae* antibiotic(s) found in *Paenibacillus larvae* subsp. *larvae* subsp. *pulvifaciens*.
11. The composition of claim 7, wherein the antibiotic(s) are active against one or more of *Escherichia coli*, *Salmonella typhimurium*, *Pseudomonas putida*, *Pseudomonas aerugenosa*, *Micrococcus luteus*, *Bacillus cereus*, *Bacillus subtilis*, *Paenibacillus alvei*, *Paenibacillus larvae* subsp. *larvae* subsp. *larvae*, *Paenibacillus apiarius*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Yersinia enterocolitica*, and *Melissococcus pluton*.
12. The composition of claim 7, wherein the microorganism(s) comprise bacteria.
13. The composition of claim 12, wherein the bacteria comprise bacterial endospores.
14. The composition of claim 13, wherein the bacterial endospores are washed and/or concentrated.
15. The composition of claim 12, wherein the bacteria comprise a *Paenibacillus* spp.

16. The composition of claim 15, wherein the *Paenibacillus* spp. is:

- (a) a subspecies of *Paenibacillus larvae*; or
- (b) *P. alvei*.



(ix) EVIDENCE APPENDIX

1. Hornitzky, Michael, "Oxytetracycline sensitivity of *Paenibacillus larvae* subsp. *larvae* subsp. *larvae* isolates," Australian Government Rural Industries Research and Development Corporation, RIRDC Publication No. 05/021, RIRDC Project No. DAN-219A, pp. 1-6 (January 2005).
2. Genersch *et al.*, "Strain- and Genotype-Specific Differences in Virulence of *Paenibacillus larvae* subsp. *larvae*, a Bacterial Pathogen Causing American Foulbrood Disease in Honeybees," Applied and Environmental Microbiology, 71(11), pp. 7551-7555 (2005).
3. Alippi *et al.*, "Differentiation of *Paenibacillus larvae* subsp. *larvae* subsp. *larvae*, the Cause of American Foulbrood of Honeybees, by Using PCR and Restriction Fragment Analysis of Genes Encoding 16S rRNA," Applied and Environmental Microbiology, 68(7), pp. 3655-3660 (2002).
4. Evans *et al.*, "Antagonistic interactions between honey bee bacterial symbionts and implications for disease," BMC Ecology, 6(4), pp. 1-9, (2006).
5. Neuendorf *et al.*, "Biochemical characterization of different genotypes of *Paenibacillus larvae* subsp. *larvae* subsp. *larvae*, a honey bee bacterial pathogen," Microbiology, 150, pp. 2381-2390 (2004).
6. "*Paenibacillus larvae* subsp. *larvae* subsp. *larvae*," from DSMZ-List of Microbial Species: *Paenibacillus larvae* subsp. *larvae* subsp. *larvae* (Bacteria) by Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH.
7. "American Foulbrood," VITA, pp. 1-3,
<http://www.beekeeping.com/vita/disease/American.htm>.
8. Honey Bee Research, pp. 1-2, <http://www.ars.usda.gov/research/projects/projects.htm>

(x) RELATED PROCEEDINGS APPENDIX

NONE